UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 31, 2024

Dyne Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39509**	**36-4883909**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1560 Trapelo Road **Waltham, Massachusetts**		**02451**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's telephone number, including area code: (781) 786-8230

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	DYN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On September 3, 2024, Dyne Therapeutics, Inc. (the "Company") announced that on August 31, 2024, Jonathan McNeill, M.D., the Company's Chief Business Officer, and Susanna High, the Company's Chief Operating Officer, each notified the Company of their intention to resign their employment. Dr. McNeill's resignation is effective September 3, 2024, and Ms. High's resignation is effective October 1, 2024.

In connection with their resignations, Dr. McNeill and Ms. High also entered into consulting agreements with the Company under which they each agreed to provide consulting and advisory services to the Company following the effective date of their resignations of employment until December 31, 2024.

Item 7.01 Regulation FD Disclosure.

On September 3, 2024, the Company issued a press release announcing new clinical data from its ongoing Phase 1/2 DELIVER clinical trial of DYNE-251 in patients with Duchenne muscular dystrophy ("DMD") who are amenable to exon 51 skipping. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

Leadership Changes

On September 3, 2024, the Company issued a press release announcing the hiring of Doug Kerr as chief medical officer, Johanna Friedl-Naderer as chief commercial officer and Lucia Celona as chief human resources officer and the resignations of Dr. McNeill, Ms. High and Wildon Farwell, the chief medical officer.

New Clinical Data from Phase 1/2 DELIVER Trial of DYNE-251 in DMD

On September 3, 2024, the Company issued a press release announcing new clinical data from its ongoing Phase 1/2 DELIVER clinical trial of DYNE-251 in patients with DMD who are amenable to exon 51 skipping. The Company also provided a safety update for its ongoing Phase 1/2 ACHIEVE clinical trial of DYNE-101 in patients with myotonic dystrophy type 1 ("DM1").

The assessment of the DELIVER trial evaluating DYNE-251 includes 6-month biomarker and functional data from 8 male participants enrolled in the 20 mg/kg (approximate PMO dose) cohort who were randomized to receive DYNE-251 or placebo once every four weeks and 12-month functional data from 6 participants who were randomized in the 10 mg/kg (approximate PMO dose) cohort. (During the open label extension period, all participants in the 10 mg/kg cohort were dose escalated to 20 mg/kg Q4W regimen.) DYNE-251 demonstrated dose dependent exon skipping and dystrophin expression and improvement in multiple functional endpoints in both cohorts.

Key findings include:

- **Dystrophin expression**: DYNE-251 demonstrated the highest level of dystrophin expression for an exon 51 skipping therapy as measured by Western blot. Patients treated with 20 mg/kg of DYNE-251 Q4W had a mean absolute dystrophin expression of 3.71% of normal (unadjusted for muscle content), more than 10-fold higher than the 0.3% reported in a clinical trial of the weekly standard of care, eteplirsen. When adjusting for muscle content, the DYNE-251 treated group reached 8.72% mean absolute dystrophin, which is greater than levels reported by peptide conjugate PMOs in clinical development. However, the DELIVER trial does not compare DYNE-251 to eteplirsen or SRP-5051, and no head-to-head trials have

been conducted comparing DYNE-251 to eteplirsen or SRP-5051. Eteplirsen data and SRP-5051 data may not be directly comparable to the DELIVER data due to differences between the trials in trial protocols, dosing regimens, methodologies for calculating muscle content adjusted dystrophin and patient populations. Accordingly, these cross-trial comparisons may not be reliable.

- **Function**: Meaningful improvements in multiple functional endpoints were observed in both the 20 mg/kg and 10 mg/kg DYNE-251 Q4W groups, including North Star Ambulatory Assessment ("NSAA"), Stride Velocity 95th Centile ("SV95C"), 10-Meter Walk/Run Time ("10-MWR"), Time to Rise from Floor. The 10 mg/kg cohort showed continued improvement in all reported measures from 6 months to 12 months.
    - SV95C is a digital objective outcome measure of ambulatory performance in patients' normal daily environment and is approved as a primary endpoint for DMD clinical trials in Europe. The change from baseline observed in both the 10 mg/kg and 20 mg/kg cohorts of DELIVER met the published minimal clinically important difference ("MCID") as defined by the European Medicines Agency.
- **Safety and Tolerability**: Safety and tolerability data are based on 54 participants enrolled in the DELIVER trial. DYNE-251 demonstrated a favorable safety profile and the majority of treatment emergent adverse events were mild or moderate, as of the safety data cut-off date of August 21, 2024. No related serious treatment emergent adverse events were identified other than in two participants at the 40 mg/kg dose level which events were potentially related to study drug. Both participants have recovered. Approximately 675 doses have been administered to date in the DELIVER trial, representing over 50 patient-years of follow-up.

Key Milestones for DELIVER and ACHIEVE Trials

- Based on these data and regulatory interactions, the Company is initiating registrational cohorts in the DELIVER trial and plans to provide an update on the path to registration by the end of 2024.
- The Company is also executing its ongoing Phase 1/2 ACHIEVE clinical trial of DYNE-101 in DM1. The safety profile of DYNE-101 continues to be favorable and includes safety data up to the 6.8 mg/kg Q8W cohort, as of the safety data cut-off date of August 20, 2024. The Company continues to engage with global regulators, including the U.S. Food and Drug Administration, and plans to provide an update on the path to registration for DYNE-101, including additional clinical data, by the end of 2024.

Data Presentation

On September 3, 2024, the Company made available a presentation to discuss the clinical data from the DELIVER clinical trial. A copy of the presentation is filed as Exhibit 99.2 hereto and is incorporated herein by reference.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company's strategy, future operations, prospects and plans, objectives of management, the potential of the FORCE platform, the anticipated timelines for reporting additional data from the ACHIEVE and DELIVER clinical trials and initiating registrational cohorts, expectations regarding the timing and outcome of interactions with global regulatory authorities and the availability of accelerated approval pathways for DYNE-101 and DYNE-251, and plans to provide future updates on pipeline programs, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable

terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and the Company's ability to enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from the Company's clinical trials and acceptance of the Company's clinical programs and the regulatory approval process; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission ("SEC"), including the Company's most recent Form 10-Q and in subsequent filings the Company may make with the SEC. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

Exhibit Number	Description
99.1	Press Release, dated September 3, 2024.
99.2	Presentation, dated September 3, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DYNE THERAPEUTICS, INC.

Date: September 3, 2024

By: /s/ John Cox
Name: John Cox
Title: President and Chief Executive Officer

Dyne Therapeutics Announces New Clinical Data from Phase 1/2 DELIVER Trial of DYNE-251 in Duchenne Muscular Dystrophy Demonstrating Unprecedented Dystrophin Expression and Functional Improvement in Multiple Cohorts

- Initiating Registrational Cohorts with Update on Path to Registration by Year-End 2024 -

- Virtual Investor Event Today at 8:00 a.m. ET -

WALTHAM, Mass., September 3, 2024 – Dyne Therapeutics, Inc. (Nasdaq: DYN), a clinical-stage muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases, today announced new clinical data from its ongoing Phase 1/2 DELIVER trial of DYNE-251 in patients with Duchenne muscular dystrophy (DMD) who are amenable to exon 51 skipping demonstrating unprecedented dystrophin expression and functional improvement in multiple cohorts.

"We believe these data reinforce the opportunity to transform the treatment paradigm for individuals living with Duchenne. In DELIVER, DYNE-251 achieved the highest level of dystrophin expression reported for an exon 51 skipping therapy and improvement in multiple functional endpoints across multiple cohorts that continued with time on therapy," said Wildon Farwell, M.D., MPH, chief medical officer of Dyne. "Our goal has always been to drive dystrophin levels that lead to functional benefit for patients – these data suggest that the distribution across cardiac, diaphragm and other skeletal muscles observed preclinically with the FORCE platform is translating in the clinic. Importantly, treatment with DYNE-251 resulted in meaningful improvements in SV95C, a digital outcome measure approved as a primary endpoint for Duchenne clinical trials in Europe. With these exciting data, we are moving quickly to initiate registrational cohorts in DELIVER, and we continue to pursue expedited approval pathways and plan to provide an update on our path to registration by the end of this year."

This assessment of the DELIVER trial evaluating DYNE-251 includes 6-month biomarker and functional data from 8 male patients enrolled in the 20 mg/kg (approximate PMO dose) cohort who were randomized to receive DYNE-251 or placebo once every four weeks, and 12-month functional data from 6 participants in the 10 mg/kg cohort.[1] DYNE-251 demonstrated dose dependent exon skipping and dystrophin expression and improvement in multiple functional endpoints in both cohorts. Key findings include:

- **Dystrophin expression:** DYNE-251 demonstrated unprecedented dystrophin expression as measured by Western blot. Patients treated with 20 mg/kg of DYNE-251 Q4W had a mean absolute dystrophin expression of 3.71% of normal (unadjusted for muscle content), more than 10-fold higher than the 0.3% reported in a clinical trial of the weekly standard of care, eteplirsen.[2] When adjusting for muscle content, the DYNE-251 treated group reached 8.72% mean absolute dystrophin, which is greater than levels reported by peptide conjugate PMOs in clinical development.[3]
- **Function:** Meaningful improvements in multiple functional endpoints were observed in both the 20 mg/kg and 10 mg/kg DYNE-251 Q4W groups, including North Star Ambulatory Assessment (NSAA), Stride Velocity 95th Centile (SV95C), 10-Meter Walk/Run Time (10-MWR), Time to Rise from Floor. The 10 mg/kg cohort showed continued improvement in all reported measures from 6 months to 12 months.[1]

- SV95C is a digital objective outcome measure of ambulatory performance in patients' normal daily environment and is approved as a primary endpoint for Duchenne clinical trials in Europe. The change from baseline observed in both the 10 mg/kg and 20 mg/kg cohorts of DELIVER met the published minimal clinically important difference (MCID) as defined by the European Medicines Agency.

- **Safety and Tolerability:** Safety and tolerability data are based on 54 participants enrolled in the DELIVER trial. DYNE-251 demonstrated a favorable safety profile and the majority of treatment emergent adverse events were mild or moderate.[4] No related serious treatment emergent adverse events have been identified other than in two participants at the 40 mg/kg dose level with events potentially related to study drug and both participants have recovered. Approximately 675 doses have been administered to date in the DELIVER trial, representing over 50 patient-years of follow-up.

Key Milestones for DELIVER and ACHIEVE Trials

- Based on these data and regulatory interactions, Dyne is initiating registrational cohorts in the DELIVER trial and plans to provide an update on the path to registration by the end of 2024.
- Dyne is also executing its ongoing Phase 1/2 ACHIEVE clinical trial of DYNE-101 in myotonic dystrophy type 1. The safety profile of DYNE-101 continues to be favorable and includes safety data up to the 6.8 mg/kg Q8W cohort.[5] The company continues to engage with global regulators, including the U.S. Food and Drug Administration, and plans to provide an update on the path to registration for DYNE-101, including additional clinical data, by the end of 2024.

Virtual Investor Event

Dyne will host a video webcast event to discuss these DELIVER data today, September 3, 2024, at 8:00 a.m. ET and a replay will be accessible for 90 days following the presentation. An accompanying slide presentation for the event and an updated corporate presentation will also be available. To access these presentations and register for the live webcast and replay, please visit the Investors & Media section of Dyne's website at https://investors.dyne-tx.com/news-and-events/events-and-presentations and the live event may also be accessed here.

About the DELIVER Trial

DELIVER is a Phase 1/2 global clinical trial evaluating DYNE-251, consisting of a 24-week multiple ascending dose (MAD) randomized placebo-controlled period, a 24-week open-label extension and a 96-week long-term extension. The trial, which is designed to be registrational, is enrolling ambulant and non-ambulant males with Duchenne muscular dystrophy (DMD) who are ages 4 to 16 and have mutations amenable to exon 51 skipping. The primary endpoints are safety, tolerability and change from baseline in dystrophin levels as measured by Western blot. Secondary endpoints include measures of muscle function, exon skipping and pharmacokinetics. For more information on the DELIVER trial, visit https://www.clinicaltrials.gov/ (NCT05524883).

About DYNE-251

DYNE-251 is an investigational therapeutic being evaluated in the Phase 1/2 global DELIVER clinical trial for people living with DMD who are amenable to exon 51 skipping. DYNE-251 consists of a phosphorodiamidate morpholino oligomer (PMO) conjugated to a fragment antibody (Fab) that binds to the transferrin receptor 1 (TfR1) which is highly expressed on muscle. It is designed to enable targeted muscle tissue delivery and promote exon skipping in the nucleus, allowing muscle cells to create a truncated, functional dystrophin protein, with the goal of stopping or reversing disease progression. DYNE-251 has been granted fast track, orphan drug and rare pediatric disease designations by the U.S. Food and Drug Administration for the treatment of DMD mutations amenable to exon 51 skipping.

In addition to DYNE-251, Dyne is building a global DMD franchise and has preclinical programs targeting other exons, including 53, 45 and 44.

About Duchenne Muscular Dystrophy (DMD)

DMD is a rare disease caused by mutations in the gene that encodes for dystrophin, a protein critical for the normal function of muscle cells. These mutations, the majority of which are deletions, result in the lack of dystrophin protein and progressive loss of muscle function. DMD occurs primarily in males and affects an estimated 12,000 to 15,000 individuals in the U.S. and 25,000 in Europe. Loss of strength and function typically first appears in pre-school age boys and worsens as they age. As the disease progresses, the severity of damage to skeletal and cardiac muscle often results in patients experiencing total loss of ambulation by their early teenage years and includes worsening cardiac and respiratory symptoms and loss of upper body function by the later teens. There is no cure for DMD and currently approved therapies provide limited benefit.

About Dyne Therapeutics

Dyne Therapeutics is a clinical-stage muscle disease company focused on advancing innovative life-transforming therapeutics for people living with genetically driven diseases. With its proprietary FORCE™ platform, Dyne is developing modern oligonucleotide therapeutics that are designed to overcome limitations in delivery to muscle tissue. Dyne has a broad pipeline for serious muscle diseases, including clinical programs for myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD) and a preclinical program for facioscapulohumeral muscular dystrophy (FSHD). For more information, please visit https://www.dyne-tx.com/, and follow us on X, LinkedIn and Facebook.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Dyne's strategy, future operations, prospects and plans, objectives of management, the potential of the FORCE platform, the anticipated timelines for reporting additional data from the ACHIEVE and DELIVER clinical trials and initiating registrational cohorts, expectations regarding the timing and outcome of interactions with global regulatory authorities and the availability of accelerated approval pathways for DYNE-101 and DYNE-251, and plans to provide future updates on pipeline programs, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Dyne may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and Dyne's ability to enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials and acceptance of Dyne's clinical programs and the regulatory approval process; whether Dyne's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Dyne's filings with the Securities and Exchange Commission (SEC), including the Company's most recent Form 10-Q and in subsequent filings Dyne may make with the SEC. In addition, the forward-looking statements included in this press release represent Dyne's views as of the date of this press release. Dyne anticipates that subsequent events and developments will cause its views to change. However, while Dyne may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Dyne's views as of any date subsequent to the date of this press release.

1. During the OLE period, all participants in 10 mg/kg cohort were dose escalated to 20 mg/kg Q4W regimen.
2. No head-to-head trials have been conducted comparing DYNE-251 to eteplirsen. Eteplirsen data may not be directly comparable due to differences in trial protocols, dosing regimens and patient populations. Accordingly, these cross-trial comparisons may not be reliable. Eteplirsen data from J Neuromuscul Dis. 2021; 8(6): 989–1001.

3. No head-to-head trials have been conducted comparing DYNE-251 to SRP-5051. SRP-5051 data may not be directly comparable due to differences in trial protocols, dosing regimens, methodologies for calculating muscle content adjusted dystrophin and patient populations. Accordingly, these cross-trial comparisons may not be reliable. SRP-5051 data from Clinical Update: MOMENTUM (Study SRP-5051-201, Part B) Jan. 29, 2024.
4. DYNE-251 safety data as of August 21, 2024.
5. DYNE-101 safety data as of August 20, 2024.

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Exhibit 99.2

ACHIEVE

Dyne THERAPEUTICS

DELIVER

Achieving the Promise of FORCE *to Deliver for Patients*

FORCE

DELIVER CLINICAL UPDATE | SEPTEMBER 3, 2024

Forward-Looking Statements & Disclaimer

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding Dyne's strategy, future operations, prospects and plans, objectives of management, the potential of the FORCE platform, the anticipated timelines for reporting additional data from the ACHIEVE and DELIVER clinical trials and initiating registrational cohorts, expectations regarding the timing and outcome of interactions with global regulatory authorities and the availability of accelerated approval pathways for DYNE-101 and DYNE-251, and plans to provide future updates on pipeline programs, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Dyne may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and Dyne's ability to enroll patients in clinical trials; whether results from preclinical studies and initial data from early clinical trials will be predictive of the final results of the clinical trials or future trials; uncertainties as to the FDA's and other regulatory authorities' interpretation of the data from Dyne's clinical trials and acceptance of Dyne's clinical programs and the regulatory approval process; whether Dyne's cash resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Dyne's filings with the Securities and Exchange Commission (SEC), including the Company's most recent Form 10-Q and in subsequent filings Dyne may make with the SEC. In addition, the forward-looking statements included in this presentation represent Dyne's views as of the date of this presentation. Dyne anticipates that subsequent events and developments will cause its views to change. However, while Dyne may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Dyne's views as of any date subsequent to the date of this presentation.

This presentation also contains estimates, projections and other statistical data made by independent parties and by the Company relating to market size and growth and other data about the Company's industry and business. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. The Company has not independently verified the accuracy and completeness of the information obtained by third parties included in this presentation. In addition, projections, assumptions and estimates of the Company's future performance and the future performance of the markets in which the Company operates are necessarily subject to a high degree of uncertainty and risk.

Program

Opening remarks
John Cox, President & CEO

DYNE-251 DELIVER Trial in DMD Data
Wildon Farwell, M.D., MPH, Chief Medical Officer

Closing Remarks
John Cox, President & CEO

Q&A

OUR MISSION

Life-transforming therapies

for patients with serious muscle diseases

Committed to Building the World's Leading Muscle Disease Company

DELIVER CLINICAL UPDATE

- Potential to transform the treatment paradigm for people living with DMD
- Best-in-class dystrophin resulting in unprecedented improvements in multiple functional outcomes, including NSAA and SV95C, in multiple cohorts[1]
- Favorable safety profile to date[2]

LEADERSHIP UPDATE

- Proven team of biopharma executives to deliver on Dyne's next chapter
  - Doug Kerr (CMO), Johanna Friedl-Naderer (CCO), and Lucia Celona (CHRO) bring decades of global experience across rare disease clinical development, commercial execution, and organizational builds
- Accelerating commercial preparedness across key functions

NEXT STEPS

- Continue to pursue expedited approval pathways globally
- Initiating registrational cohorts in DELIVER trial of DYNE-251 in DMD
- Provide update on the path to registration for DYNE-101 and DYNE-251 by the end of 2024

1. NSAA: North Star Ambulatory Assessment; SV95C: Stride Velocity 95th Centile. 2. Data as of August 21, 2024.

Program

Opening remarks
John Cox, President & CEO

DYNE-251 DELIVER Trial in DMD Data
Wildon Farwell, M.D., MPH, Chief Medical Officer

Closing Remarks
John Cox, President & CEO

Q&A

Building a Global DMD Franchise of Transformative Therapies

Overview
- Mutation in the *DMD* gene that encodes for dystrophin
- Onset in first few years of life
- Life expectancy ~30 years

Clinical Presentation
- Muscle weakness
- Progressive loss of function
- Loss of ambulation
- Respiratory/cardiac failure

Population
- ~12,000 - 15,000 (US)
- ~ 25,000 (Europe)

Current Approved Exon 51 Therapies Only Increased Dystrophin Production <1%

OUR APPROACH

Potential Best-in-class Targeted Exon Skipping

Increase dystrophin expression and enable less frequent dosing to potentially **stop or reverse disease progression**

Phase 1/2 Clinical Trial to Evaluate DYNE-251 in Patients with DMD

DELIVER

Population

- Male patients with DMD with mutations amenable to exon 51 skipping therapy
- Ages 4 to 16 years
- Ambulant and non-ambulant

Primary Endpoints

- Safety and tolerability
- Change from baseline in dystrophin protein levels by Western Blot

Additional Endpoints

- Pharmacokinetics
- Change from baseline of:
  - Exon 51 skipping levels
  - Muscle tissue PDPF
  - Multiple assessments of muscle function, including NSAA score, SV95C and certain timed functional tests

Stages of DELIVER

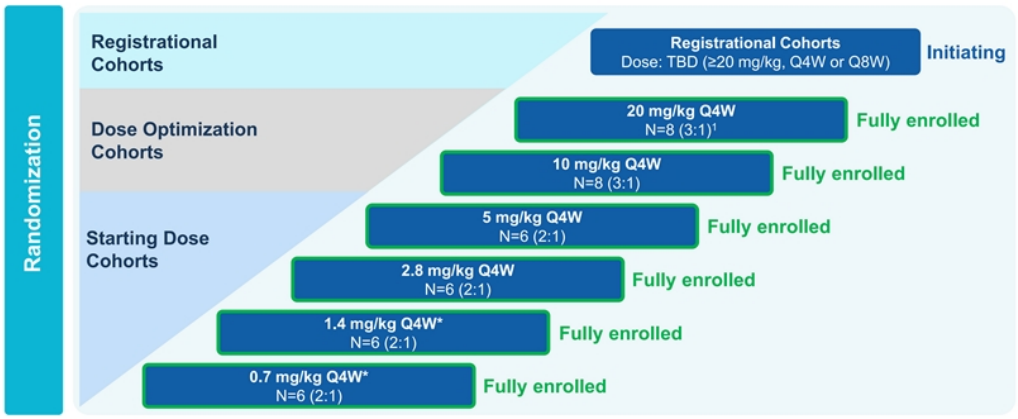
- Multiple Ascending Dose (MAD): 24 weeks
- Open-Label Extension (OLE): 24 weeks
- Long-Term Extension (LTE): 96 weeks

Note: Additional endpoints include select secondary and exploratory endpoints
PDPF: percent dystrophin-positive fibers; NSAA: North Star Ambulatory Assessment; SV95C: Stride Velocity 95th Centile.

DELIVER Trial Design

DELIVER

Global, Randomized, Placebo-Controlled Stage Evaluating Administration of DYNE-251 in Ambulant and Non-Ambulant Male DMD Patients with Mutations Amenable to Exon 51 Skipping Therapy



MAD Study Details

- IV administration of DYNE-251 or placebo every 4 weeks or every 8 weeks
- Muscle biopsies: Baseline and 24 weeks[2]
- Patients in MAD study escalated to highest tolerable dose in OLE and LTE

Global Trial Designed to be Registrational and to Enable Rapid Achievement of Predicted Pharmacologically Active Dose Levels

Doses provided refer to PMO component of DYNE-251. Cohorts randomized to active arm or placebo.
1. All participants in DELIVER starting dose and dose optimization cohorts are currently receiving 20 mg/kg dose, including 32 participants dose escalated following the placebo-controlled period from starting doses lower than 20 mg/kg and 14 participants initiated at 40 mg/kg who are now being dosed at 20 mg/kg following evaluation of the safety profile at 40 mg/kg. 2. Muscle biopsies taken at baseline and 24 weeks in 2.8 mg/kg Q4W cohort to 20 mg/kg Q4W cohort; biopsies not taken in 0.7 mg/kg and 1.4 mg/kg cohorts.

DELIVER Baseline Participant Characteristics: By Cohort

mean (SD) or n(%)	0.7 mg/kg (N=6)	1.4 mg/kg (N=6)	2.8 mg/kg (N=6)	5 mg/kg (N=6)	10 mg/kg (N=8)	20 mg/kg (N=8)
Age (years)	10.8 (2.2)	7.8 (3.3)	10.7 (2.9)	8.3 (2.8)	6.6 (2.2)	8.1 (2.4)
BMI (kg/m^2)	19.5 (3.4)	18.6 (2.3)	22.6 (6.3)	20.9 (1.6)	18.3 (3.2)	18.6 (5.1)
Age of Symptom Onset (years)	3.7 (1.8)	4.5 (2.1)	2.8 (1.8)	3.7 (3.1)	2.8 (1.6)	2.9 (2.0)
Corticosteroid dosing regimen (n (%))[1] Daily Other	 4 (66.7%) 2 (33.3%)	 4 (66.7%) 3 (50.0%)	 5 (83.3%) 2 (33.3%)	 6 (100.0%) 0	 8 (100.0%) 0	 8 (100.0%) 2 (25.0%)
Prior DMD Therapy (n (%)) Eteplirsen Other	 4 (66.7%) 2 (33.3%)	 2 (33.3%) 1 (16.7%)	 5 (83.3%) 0	 1 (16.7%) 0	 1 (12.5%) 1 (12.5%)	 0 2 (25.0%)
NSAA Total Score	22.2 (7.2)	22.8 (10.5)	20.3 (9.0)	21.0 (7.0)	25.3 (6.4)	15.6 (5.1)
10 Meter Run/Walk (sec)	6.1 (1.5)	6.3 (5.2)	6.9 (3.6)	5.1 (1.5)	4.6 (1.9)	7.7 (3.8)
Time Rise From Floor (sec)	8.5 (4.0)	3.1 (0.3)	6.9 (4.9)	5.0 (2.6)	6.3 (5.6)	5.1 (2.3)
Stride Velocity 95th Percentile (m/sec)	N/A	N/A	N/A	N/A	1.9 (0.5)	1.4 (0.5)

Note: Q4W and placebo arms are reported together for baseline characteristics. N/A: not applicable as data not collected.
1. Historical corticosteroid regimen based on medical history; a participant can be counted in multiple categories.

DYNE-251 Safety Profile Is Favorable to Date

Summary of Treatment Emergent Adverse Events (TEAEs)[1]

TEAE Category	Participants with ≥1 TEAE – n (%)								
	0.7mg/kg Q4W N=6	1.4 mg/kg Q4W N=6	2.8 mg/kg Q4W N=6	5 mg/kg Q4W N=6	10 mg/kg Q4W N=8	20 mg/kg Q4W N=8	40 mg/kg Q8W[7] N=8	40 mg/kg Q4W[7] N=6	Overall[1] N=54
Any TEAE	6 (100%)	6 (100%)	4 (67%)	6 (100%)	7 (88%)	8 (100%)	6 (75%)	4 (67%)	47 (87%)
Any related TEAE	3 (50%)	3 (50%)	0	6 (100%)	3 (38%)	4 (50%)	1 (13%)	2 (33%)	22 (41%)
Any serious TEAE	0	0	1 (17%)	0	0	1 (13%)	2 (25%)	2 (33%)	6 (11%)
Any serious related TEAE	0	0	0	0	0	0	0	2 (33%)	2 (4%)
Any TEAE leading to withdrawal	0	0	0	0	0	0	0	0	0
Any TEAE leading to death	0	0	0	0	0	0	0	0	0

Most TEAEs Were Mild or Moderate in Intensity

- 3 serious TEAEs potentially related to study drug in two participants
  - Acute kidney injury (1); thrombocytopenia (1)[2]
  - Pancytopenia (1)[3]
- 6 serious TEAEs unrelated to study drug
  - Dehydration due to gastroenteritis (1)
  - Femoral neck fracture (1); gastric volvulus (1)[4]
  - Tibia fracture (1)
  - Febrile convulsion (1); pyrexia (1)[5]
- Most common TEAEs (>20% participant incidence)[6]
  - Pyrexia (32%)
  - Nasopharyngitis, headache, vomiting (each 26%)
  - Fall (26%)
  - Infusion-related reaction (20%)

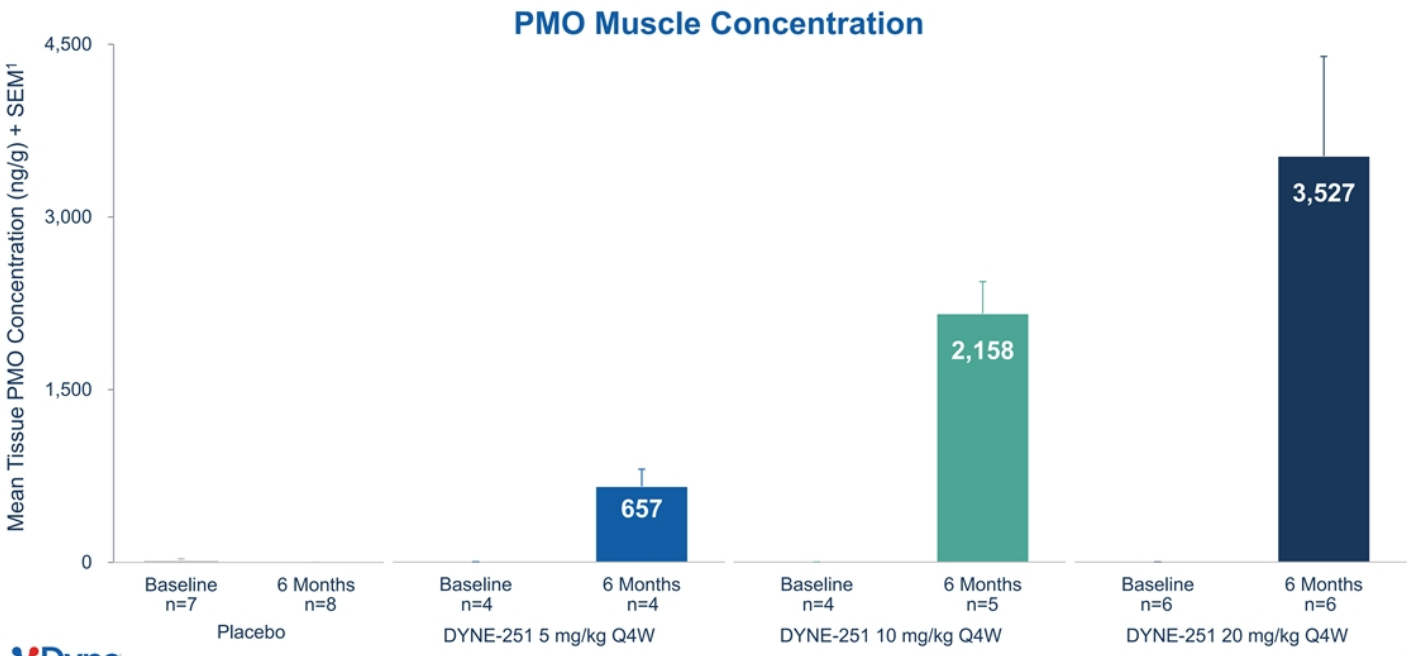
Additional Safety Data

- Other than two participants with serious TEAEs in 40 mg/kg Q4W cohort:
  - No participants have demonstrated persistent related anemia or thrombocytopenia
  - No participants have demonstrated kidney injury
- No participants have demonstrated clinically meaningful changes in electrolytes, including magnesium

~675 Doses Administered to Date Representing Over 50 Patient-Years of Follow-Up[1]

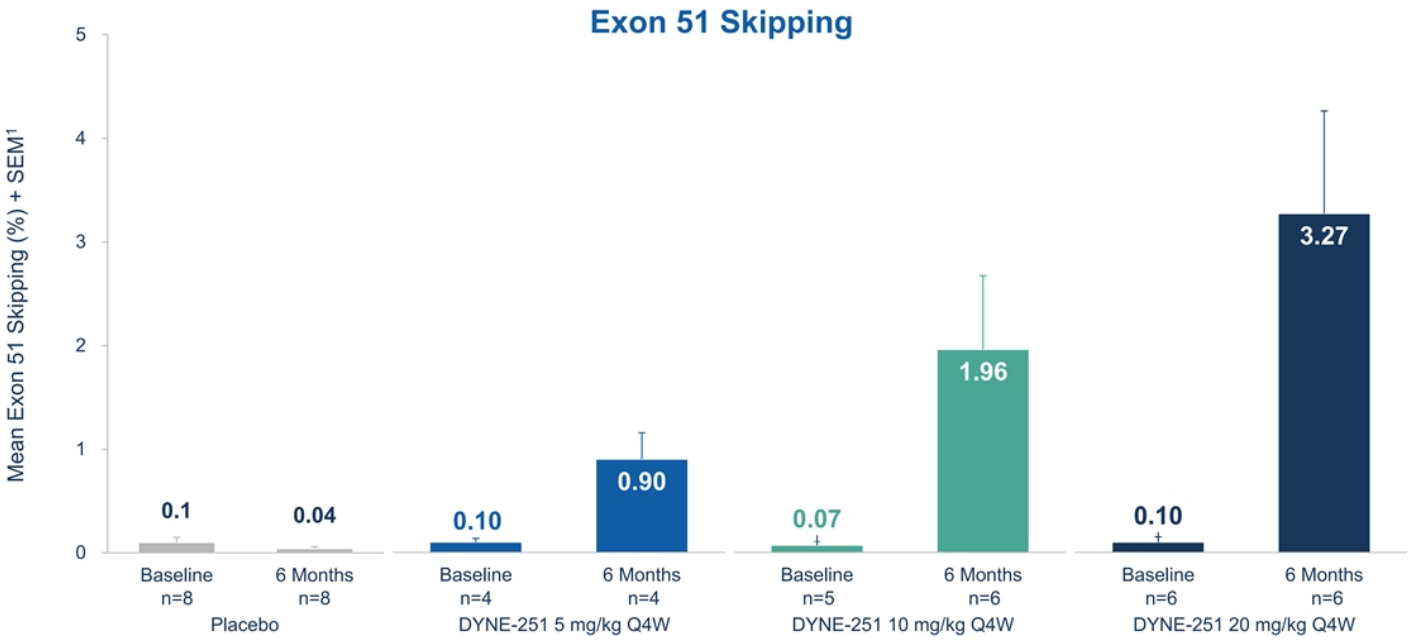
1. Data as of August 21, 2024; 2. Events have same day of onset in a single participant in the context of fever, hemolysis, diarrhea and positive blood in stool; together, these events are potentially consistent with hemolytic uremic syndrome (HUS) with a potential infectious etiology. 3. Participant had a history of hemolytic anemia of unidentified etiology prior to enrolling in DELIVER. Presented with fever and tonsilitis; all symptoms resolved without therapeutic intervention 4. Events occurred in same participant at different times; 5. Events occurred in same participant at different times; 6. All cohorts combined; preferred terms are reported; 7. 14 participants initiated at 40 mg/kg who are now being dosed at 20 mg/kg following evaluation of the safety profile at 40 mg/kg.

DYNE-251 Drove Dose Dependent Delivery of PMO to Muscle



1. DELIVER biopsy taken approximately 28 days after most recent dose; 6 months = Week 25 for DELIVER.

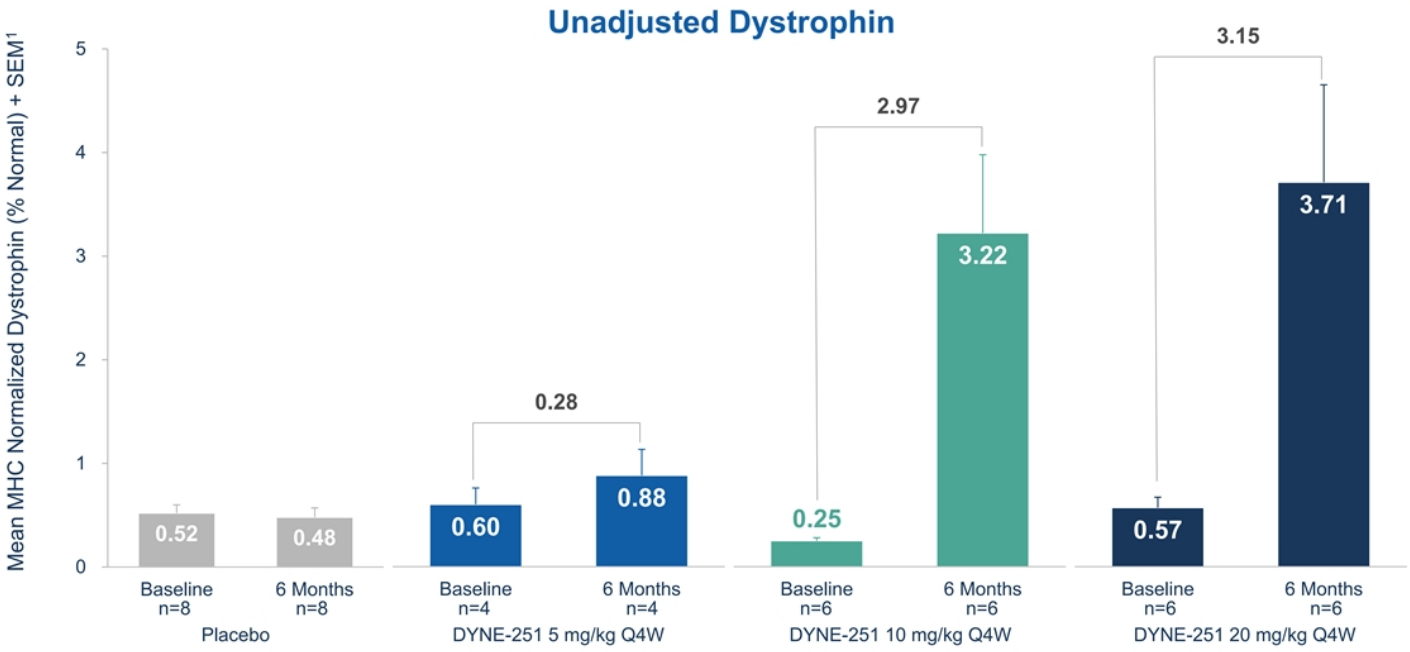
DYNE-251 Demonstrated Dose-Dependent Exon Skipping



1. DELIVER biopsy taken approximately 28 days after most recent dose; 6 months = Week 25 for DELIVER.

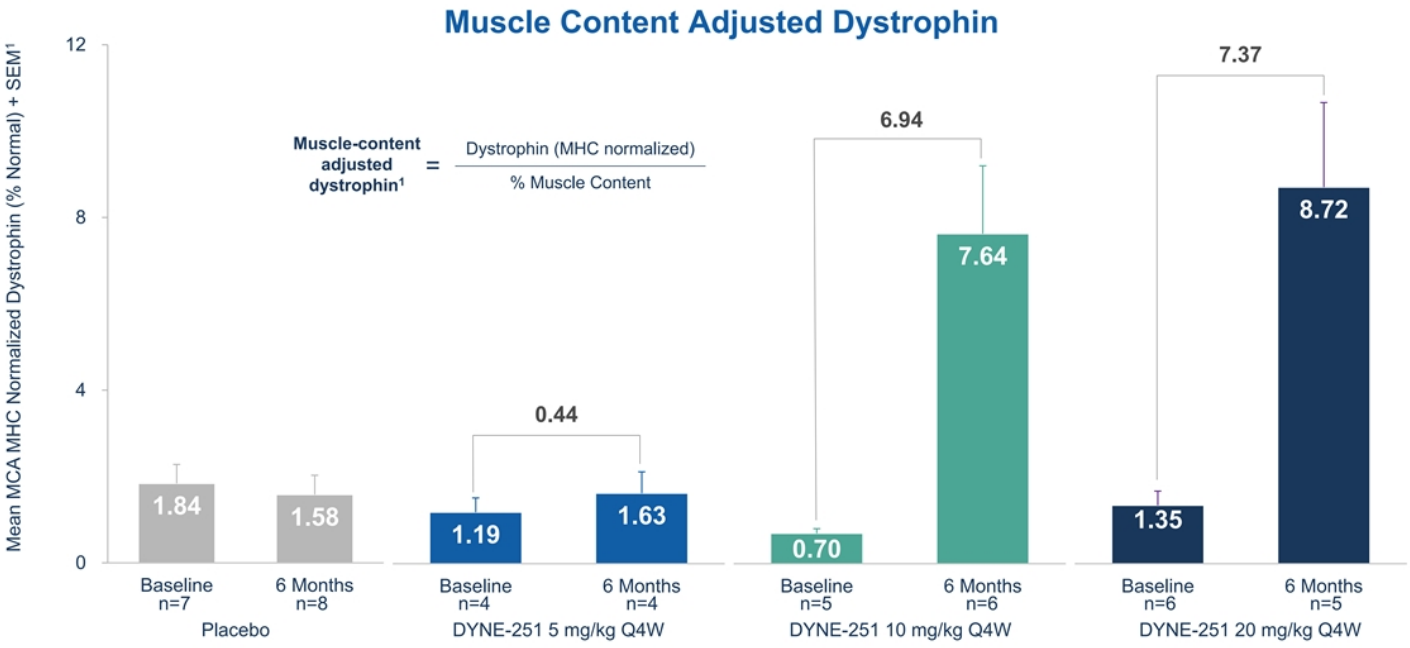
Higher Doses of DYNE-251 Continued to Drive Robust Dystrophin Expression

DYNE-251 Showed 3.7% Unadjusted Dystrophin at 6 Months



1. DELIVER biopsy taken approximately 28 days after most recent dose; 6 months = Week 25 for DELIVER.

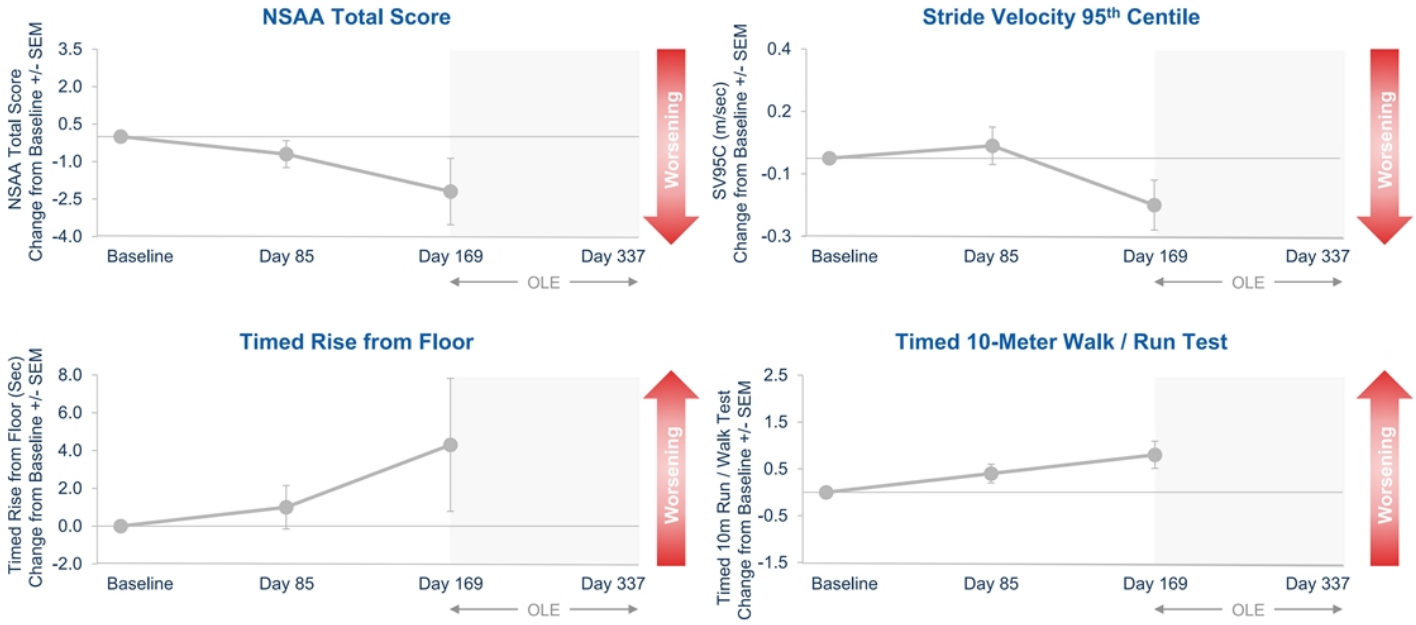
DYNE-251 Positioned as a Potentially Best-in-Class Next Generation Exon Skipper, Achieving 8.7% Muscle Content Adjusted Dystrophin at 6 Months



1. DELIVER biopsy taken approximately 28 days after most recent dose; 6 months = Week 25 for DELIVER.

Placebo Response is Consistent with Duchenne Natural History [1]

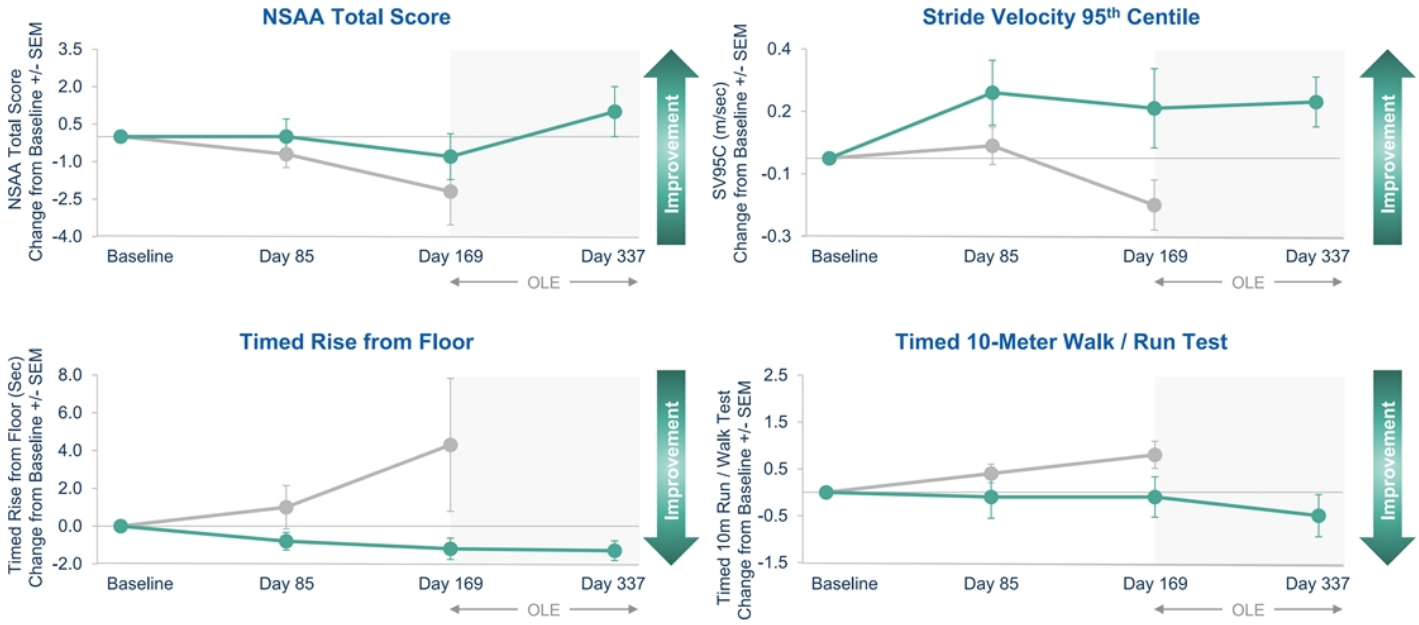
DMD Patients Worsen Across a Number of Functional Measurements Over Time



Placebo (n=6 for SV95C and n=14 for other endpoints)

1. J Neuromuscul Dis 2024;11(3):701-714; Neuromuscul Disord 2010 Nov;20(11):712-6.; PLoS One 2014 Oct 1;9(10):e108205.

Data from 10 mg/kg Cohort Highlights Extension of Effect from 6 Months to 1 Year



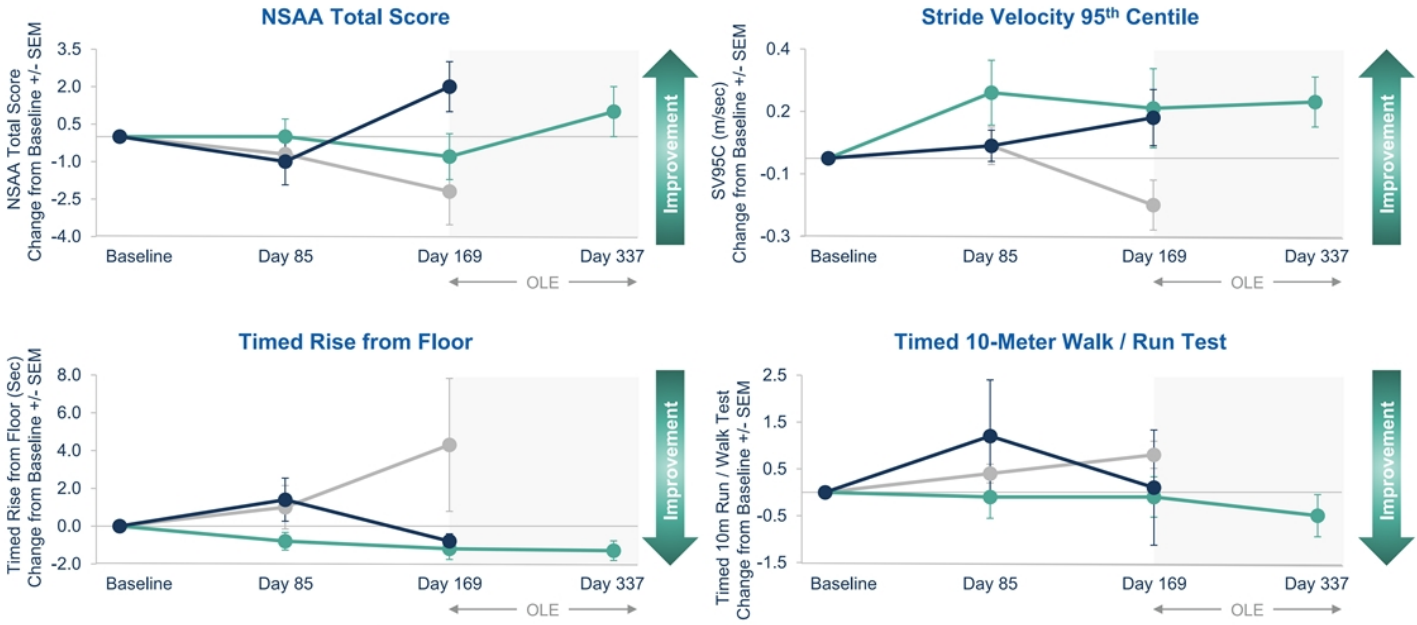
Placebo (n=6 for SV95C and n=14 for other endpoints)

DYNE-251 10 mg/kg Q4W (n = 6 for all endpoints) [1]

1. During the OLE, all participants in 10 mg/kg cohort were dose escalated to 20 mg/kg Q4W regimen.

Improvements Across Multiple Functional Endpoints in Multiple Cohorts

Baseline Values Inform Interpretation of Data; Ongoing Exploration of Longer Timepoints

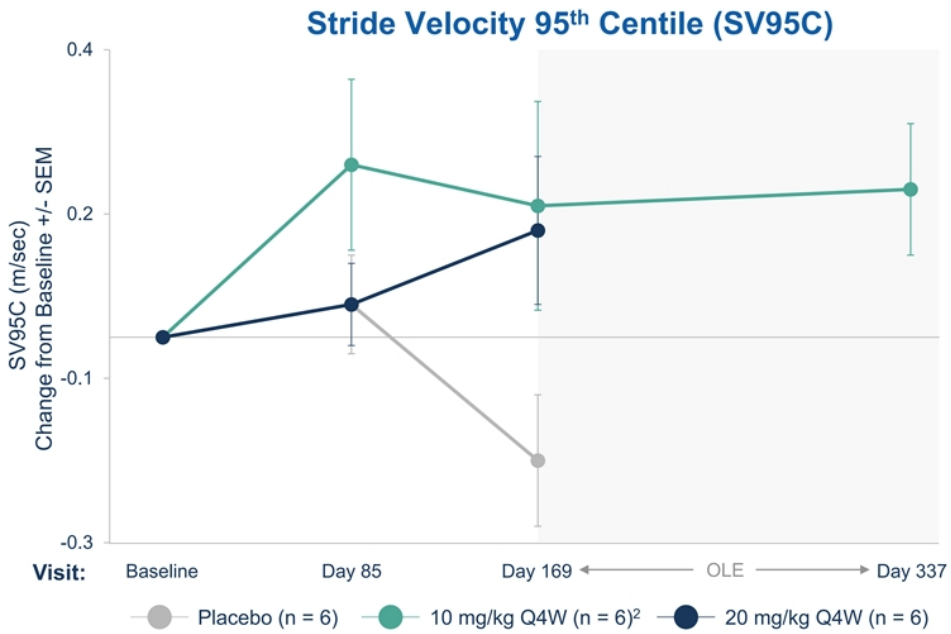


Placebo (n=6 for SV95C and n=14 for other endpoints) | DYNE-251 10 mg/kg Q4W (n = 6 for all endpoints) [1] | DYNE-251 20 mg/kg Q4W (n = 6 for all endpoints)

1. During the OLE, all participants in 10 mg/kg cohort were dose escalated to 20 mg/kg Q4W regimen.

DYNE-251 Drove Clinically Meaningful Improvements in Stride Velocity 95th Centile

SV95C is a Qualified Primary Endpoint for Duchenne Trials in Europe and Leveraged Across Global Trials



- SV95C is a digital objective endpoint of ambulatory performance in patients' normal daily environment
- Patients in DELIVER wore the device on each ankle for 3 weeks prior to the clinic visits
- The change from baseline met the published MCID by the EMA[1]

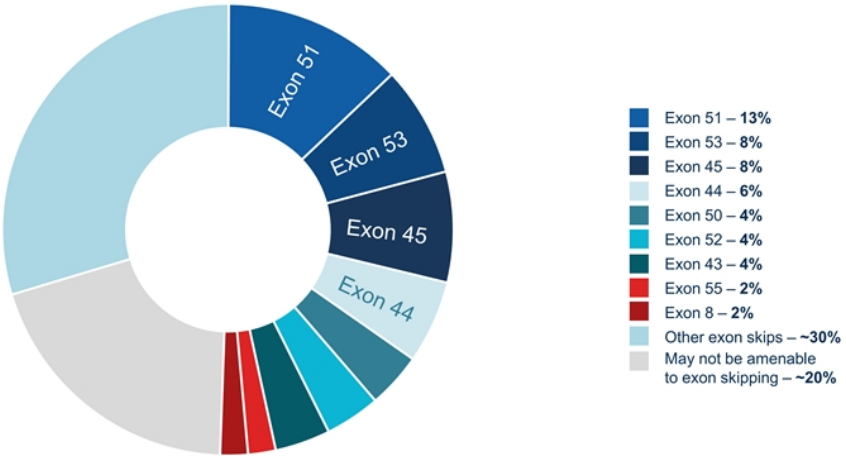
1. Minimal clinically important difference (MCID) as defined by EMA in its qualification opinion for SV95C as primary endpoint in studies in ambulatory DMD studies. 2. During the OLE, all participants in 10 mg/kg cohort were dose escalated to 20 mg/kg Q4W regimen.

Opportunity to Build a Global DMD Franchise: Leading with DYNE-251, Payloads Identified for Exons 53, 45, 44

Approximately

80% of patients

have genotypes amenable to exon skipping



Advancing DYNE-251 Towards Potentially Registrational Data Set

DELIVER

- ✓ Unprecedented level of dystrophin generated, with 3.7% unadjusted and 8.7% muscle content adjusted dystrophin
- ✓ Improvements in multiple functional outcomes, including SV95C, an approvable endpoint in Europe, in multiple cohorts
- ✓ Favorable safety profile with ~675 doses administered representing over 50 patient-years of follow up to date[1]
- ✓ Supports further development of DMD global franchise

Initiating registrational cohorts based on regulatory interactions and strength of data

Update on path to registration for DYNE-251 expected by YE 2024

1. Data as of August 21, 2024.

Program

Opening remarks
John Cox, President & CEO

DYNE-251 DELIVER Trial in DMD Data
Wildon Farwell, M.D., MPH, Chief Medical Officer

Closing Remarks
John Cox, President & CEO

Q&A

Driving Towards Potentially Transformative DM1 and DMD Therapies

ACHIEVE | DELIVER

Delivered on the Promise of FORCE: Enhanced Delivery of Therapeutics to Muscle

Compelling Impact on Key Disease Biomarkers and Improvements in Multiple Functional Endpoints in Both DM1 and DMD

Favorable Safety & Tolerability Profile

Fully Enrolled Through 6.8 mg/kg | **Initiating Registrational Cohorts**

Pursuing Expedited Approvals for Both Programs with Update on Registrational Pathway by YE 2024

Strengthening the Team to Deliver on Dyne's Next Chapter

Doug Kerr
Chief Medical Officer

Biogen · Shire · generation bio

Johanna Friedl-Naderer
Chief Commercial Officer

Biogen · VIR

Lucia Celona
Chief Human Resources Officer

Bioverativ · Biogen · Apellis · REPERTOIRE immune medicines

Proven Team of Biopharma Executives Prepared to Advance Multiple Programs to Market

Building the World's Leading Muscle Disease Company

Win in DM1, DMD, FSHD

Own Muscle Delivery & Leverage FORCE

Dynamo Culture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